

Assembly Bill No. 1382

CHAPTER 148

An act to amend Sections 2540, 2541, 2541.3, 2541.6, and 2543 of the Business and Professions Code, relating to prescription lenses.

[Approved by Governor August 23, 2006. Filed with
Secretary of State August 23, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1382, Nakanishi. Prescription lenses.

Existing law requires the State Department of Health Services, the State Board of Optometry, and the Division of Licensing and Division of Medical Quality of the Medical Board of California to prepare and adopt quality standards and adopt regulations relating to prescription ophthalmic devices, including, but not limited to, contact lenses. A violation of these regulations is a misdemeanor.

The existing Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of food, drugs, and cosmetics. Existing law prohibits a person, other than a physician and surgeon or optometrist from measuring the powers or range of human vision or determining the accommodative and refractive status of the human eye or scope of its functions in general or prescribe ophthalmic contact lenses, or plano contact lenses.

This bill would, instead, prohibit a person, other than a physician and surgeon or optometrist from measuring the powers or range of human vision or determining the accommodative and refractive status of the human eye or scope of its functions in general or prescribe ophthalmic devices, as defined.

Existing law specifies that a prescription lens is any device ordered by a physician and surgeon or optometrist, that alters or changes the visual powers of the human eye, including, but not limited by, ophthalmic and contact lenses.

This bill would, instead, specify that a prescription ophthalmic device includes specified types of contact lenses and plano contact lenses.

Existing law provides that it is a deceptive marketing practice for any licensed physician and surgeon, licensed optometrist, or registered dispensing optician to publish or cause to be published any advertisement or sales presentation relating to contact lenses representing that contact lenses may be obtained without confirmation of a valid prescription.

This bill would also make a deceptive marketing practice for any individual or entity who offers for sale plano contact lenses, as defined, to represent by any means that those lenses may be lawfully obtained without an eye examination or confirmation of a valid prescription, or may be

dispensed or furnished to a purchaser without complying with prescribed requirements.

Because a violation of regulations related to contact lenses is a crime, this bill would expand the scope of a crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature hereby finds and declares all of the following:

(1) Current California law is intended to prohibit the sale and use of “plano contact lenses,” which are zero-powered or noncorrective contact lenses intended to change the appearance of the normal eye in decorative fashion, without the required eye examination, fitting, and confirmation of a valid prescription from a licensed eye care professional.

(2) The Congress of the United States by enactment of Public Law 109-96 amended the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360j and following) to classify cosmetic plano contact lenses as medical devices requiring registration with, and approval by, the Food and Drug Administration before they may be lawfully marketed and sold in the United States.

(3) In enacting Public Law 109-96 the United States Congress made it clear that the new law is not intended to preempt or forestall individual states from enacting and enforcing laws to restrict the marketing and sale of plano contact lenses, by requiring an examination, fitting, and confirmation of a valid prescription.

(4) Notwithstanding California and federal laws to the contrary, unqualified entities persist in marketing plano contact lenses, using the Internet and unlicensed retailers to represent that these lenses may be lawfully obtained and worn without examination, fitting, and the issuance of a prescription by a licensed eye care professional.

(5) Studies show that in California these marketing efforts and representations are directed at minors, especially those with limited proficiency in English, thereby jeopardizing their eye health and vision.

(b) It is the intent of the Legislature, in enacting this act, to accomplish all of the following:

(1) Clarify the definition of plano contact lenses as prescription ophthalmic devices under California law.

(2) Incorporate the federal definition of all contact lenses as regulated medical devices.

(3) Define as a deceptive marketing practice any representation by a marketer or seller that a plano contact lens may be lawfully obtained without an eye examination or confirmation of a valid prescription, as required by California law.

(4) Encourage contact lens prescribers, fitters, dispensers, and state enforcement authorities to join in educating California contact lens consumers, especially minors, of the dangers to eye health and vision posed by purchasing and using plano contact lenses unlawfully.

SEC. 2. Section 2540 of the Business and Professions Code is amended to read:

2540. No person other than a physician and surgeon or optometrist may measure the powers or range of human vision or determine the accommodative and refractive status of the human eye or the scope of its functions in general or prescribe ophthalmic devices.

SEC. 3. Section 2541 of the Business and Professions Code is amended to read:

2541. A prescription ophthalmic device includes each of the following:

(a) Any spectacle or contact lens ordered by a physician and surgeon or optometrist, that alters or changes the visual powers of the human eye.

(b) Any contact lens described in paragraph (1) of subdivision (n) of Section 520 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360j and following).

(c) Any plano contact lens that is marketed or offered for sale in this state. “Plano contact lens” means a zero-power or noncorrective contact lens intended to change the appearance of the normal eye in a decorative fashion.

SEC. 4. Section 2541.3 of the Business and Professions Code is amended to read:

2541.3. (a) The State Department of Health Services, the State Board of Optometry and the Division of Licensing and Division of Medical Quality of the Medical Board of California shall prepare and adopt quality standards and adopt regulations relating to prescription ophthalmic devices, including, but not limited to, lenses, frames, and contact lenses. In promulgating these rules and regulations, the department and the boards shall adopt the current standards of the American National Standards Institute regarding ophthalmic materials. Nothing in this section shall prohibit the department and the boards from jointly adopting subsequent standards that are equivalent or more stringent than the current standards of the American National Standards Institute regarding ophthalmic materials.

(b) No individual or group that deals with prescription ophthalmic devices, including, but not limited to, distributors, dispensers, manufacturers, laboratories, optometrists, or ophthalmologists shall sell, dispense, or furnish any prescription ophthalmic device that does not meet the minimum standards set by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California.

(c) Any violation of the regulations adopted by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California pursuant to this section shall be a misdemeanor.

(d) Any optometrist, ophthalmologist, or dispensing optician who violates the regulations adopted by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California pursuant to this section shall be subject to disciplinary action by his or her licensing board.

(e) The State Board of Optometry or the Division of Licensing and Division of Medical Quality of the Medical Board of California may send any prescription ophthalmic device to the State Department of Health Services for testing as to whether or not the device meets established standards adopted pursuant to this section, which testing shall take precedence over any other prescription ophthalmic device testing being conducted by the department. The department may conduct the testing in its own facilities or may contract with any other facility to conduct the testing.

SEC. 5. Section 2541.6 of the Business and Professions Code is amended to read:

2541.6. No prescription ophthalmic device that does not meet the standards adopted by the State Department of Health Services, the State Board of Optometry, or the Division of Licensing and Division of Medical Quality of the Medical Board of California under Section 2541.3 shall be purchased with state funds.

SEC. 6. Section 2543 of the Business and Professions Code is amended to read:

2543. (a) Except as provided in the Nonresident Contact Lens Seller Registration Act (Chapter 5.45 (commencing with Section 2546), the right to dispense, sell or furnish prescription ophthalmic devices at retail or to the person named in a prescription is limited exclusively to licensed physicians and surgeons, licensed optometrists, and registered dispensing opticians as provided in this division. This section shall not be construed to affect licensing requirements pursuant to Section 111615 of the Health and Safety Code.

(b) It shall be considered a deceptive marketing practice for:

(1) Any licensed physician and surgeon, licensed optometrist, or registered dispensing optician to publish or cause to be published any advertisement or sales presentation relating to contact lenses that represents that contact lenses may be obtained without confirmation of a valid prescription.

(2) Any individual or entity who offers for sale plano contact lenses, as defined in subdivision (c) of Section 2541, to represent by any means that those lenses may be lawfully obtained without an eye examination or confirmation of a valid prescription, or may be dispensed or furnished to a

purchaser without complying with the requirements of Section 2562, except as provided in Chapter 5.45 (commencing with Section 2546).

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.